SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

Contact Person
Shawn Fojtik
Chief Operating Officer
CathEffects
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Device Name
Trade Name: Desai VectorCath™ Mapping Catheter and Connector Cable
Common Name: Electrode Recording Catheter and Accessory

Classification Name
Catheter, Electrode Recording
Class II, per Title 21, Code of Federal Regulations, Part 870.1220

Predicate Devices
Bard Desai Catheter Electrode K873995

Device Description
The CathEffects VectorCath Mapping Catheter is a steerable/deflectable 7 french, 125cm, closed-lumen, five-electrode catheter. The extruded polymer catheter shaft has a stainless steel reinforcing braid. It has four lateral arms that are parallel to the axis of the catheter with one gold electrode on each arm. The remaining gold electrode is located on the distal end of the catheter and is connected to a stylet. One of the lateral arms (#2) has an additional radiopaque marker so that the orientation of the second electrode is obvious under fluoroscopy.

Rotation of the handle knob causes the stylet to retract and, as a result, all four lateral arm poles to open at right angles to the axis of the catheter. When opened, the four arm electrodes protrude about 0.5 cm from the catheter shaft. The lateral arms can be refolded against the shaft axis by rotating the handle knob in the other direction. Retraction of the handle knob causes the distal end of the catheter to curve up to 180°.

The CathEffects Connector Cable provides the conduction elements from the proximal end of the Desai VectorCath Mapping Catheter handle to standard shielded ECG pins that plug into most electrophysiology recording and pacing equipment.

Indications for Use

The CathEffects Desai VectorCath™ Mapping catheter is intended for use in electrophysiology procedures to record the conduction of electrical potentials in the heart. It is also intended to be used to transmit a pacing electrical stimulus from a pulse generator to the heart during the diagnostic study.

Testing in Support of Substantial Equivalence Determination

The results of bench testing and biocompatibility testing support the substantial equivalence claims of the CathEffects Desai VectorCath™ Mapping Catheter in the above indication. Additional animal comparative testing demonstrate that the system is clinically equivalent to a standard Bard Mapping Catheter (Quadripolar).

Substantial Equivalence Conclusion

Substantial equivalence is based on the fact that the CathEffects VectorCath Mapping Catheter is identical in design, and equivalent in materials and indicated use as the Bard Desai Electrode Catheter. There are no new questions of safety or efficacy raised by the VectorCath Mapping Catheter. Therefore, it can be concluded that the VectorCath Mapping Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2001

Ms. Shawn Fojtik
Chief Operating Officer
CathEffects, LLC
1100 Melody Lane, Suite 108
Roseville, CA 95678

Re: K011361
Trade Name: CathEffects Desai VectorCath™ Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulatory Class: Class II (two)
Product Code: 74 DRF
Dated: August 10, 2001
Received: August 13, 2001

Dear Ms. Fojtik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011361

Device Name: CathEffects Desai VectorCath™ Mapping Catheter

Indications for Use

The CathEffects Desai VectorCath™ Mapping catheter is intended for use in electrophysiology procedures to record the conduction of electrical potentials in the heart. It is also intended to be used to transmit a pacing electrical stimulus from a pulse generator to the heart during the diagnostic study.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011361